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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/485,879 | 06/22/2000 | MICHAEL GIESING | 790076.401 | 6896 |

7590 12/12/2001

SEED INTELLECTUAL PROPERTY LAW GROUP
701 FIFTH AVENUE
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EXAMINER

GOLDBERG, JEANINE ANNE

| ART UNIT | PAPER NUMBER |
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1655

DATE MAILED: 12/12/2001

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action**Application No.**

09/485,879

Applicant(s)

GIESING ET AL.

Examiner

Jeanine A Goldberg

Art Unit

1655

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 29 November 2001 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 29 November 2001. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☒ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): ____.
4. ☐ Newly proposed or amended claim(s) ____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: ____.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: ____.

Claim(s) objected to: ____.

Claim(s) rejected: 18-37 and 40.

Claim(s) withdrawn from consideration: 38 and 39.

8. ☐ The proposed drawing correction filed on ____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). ____.
10. ☐ Other:

Continuation of 2. NOTE:

First, Applicant's amendment filed November 29, 2001 presents 28 new claims and only cancels 5 claims.

Further, Claims 41-43 which resemble Claims 18-20, contain limitations which are directed to dividing a plurality of cells into two fractions for analysis. The claims have also added a final process step which limits the detection of decrease risk which were not previously examined.

Moreover, Claims 44-45 are directed to organotypical genes and markers which were not part of the previously searched limitations.

Additionally, Claims 53-54 are directed to performing anticancer therapy prior to and following the steps of 41-43. The claims drawn to determining anticancer therapy were with drawn from consideration. These claims are directed to a different method which has different method steps, objectives and reagents. Thus, the limitations have not been previously searched and would require additional searches.


Claim 58 is drawn to contain limitations which were previously not presented such as organotypical genes and fractions of cells.

Claim 62 has been added which claims the determination of an ability to metastasize, which was not previously presented.

Applicant traverses the restriction to the originally presented invention arguing that it would not be an undue burden to rejoin the claims. This argument has been reviewed but is not convincing because the claims require anticancer therapy treatment. The searches are not co-extensive and are distinct for the reasons of record.

The response's arguments are directed to the newly amended claims. Applicant's argue, "that Schmitz et al. do not teach or suggest all limitations of the presently claimed invention, i.e., the claims submitted herewith by amendment are clearly distinguishable over Schmitz", "the present invention according to the amendment submitted herewith". Thus, since these claims have not been entered, the arguments are moot. However, applicant's appear to be arguing in the Schmitz rejection of the new claims that Schmitz fails to teach detecting at least one cancer-specific or cancer associated nucleic acid in a sample before cancer cells are removed from the sample and detecting a second, different cancer-specific or cancer associated nucleic acid in a sample after enrichment. Upon reviewing the claims, Claim 41 does not appear to require such a limitation. The claim discusses dividing a sample into two fractions, wherein the fractions comprise cells and the second fraction comprises at least one cell removed from said body fluid according to a method for removing cells. This does not suggest that the first fraction is assayed prior to an enrichment or cancer cell isolation step, nor does the recitation that the second fraction has been enriched. A method for removing cancer cells includes centrifugation which would pellet all cells.

However, with respect to the 102 (e) rejection, the examiner notes, that the priority date of the DE document is August 25, 1997 rather than 1998 as previously set forth. With respect to the Rimm rejection, since applicant's have not provided a translation of this document, they may not rely on the document for priority. Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15. Thus, the Rimm document is prior art until applicant's provide a translation.


W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600